DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: PRELAY™ and REZULIN™
Docket No. 97N-0145

JUL 24 1997

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,572,912, filed by Sankyo Co., Ltd., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for PRELAY™ and REZULIN™, the human drug products claimed by the patent.

The total length of the regulatory review period for PRELAY™ and REZULIN™ is 2,885 days. Of this time, 2,703 days occurred during the testing phase and 182 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 9, 1989.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 9, 1989.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: August 1, 1996.

   The applicant claims July 31, 1996, as the date the new drug applications (NDAs) for PRELAY™ (NDA 20-719) and REZULIN™ (NDA 20-720) were initially submitted. However, FDA records indicate that NDAs 20-719 and 20-720 were submitted on August 1, 1996.

3. The date the application was approved: January 29, 1997.

   FDA has verified the applicant's claim that NDAs 20-719 and 20-720 were approved on January 29, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

for Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Herbert Goodman, Esq.
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